

wherein R<sub>1</sub> = hydrogen, a cationic salt moiety, a pharmaceutically acceptable amine moiety or C<sub>1</sub>-C<sub>12</sub> alkyl cycloalkyl or aryl; and R<sup>2</sup> = Cl or CF<sub>3</sub>. (See claim 26.)

Also claimed are topical compositions for use in the method of the present invention. (See claim 34.)

The Examiner has rejected claims 26, 28-34 and 36-45 under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner states that the "Applicants' specification as filed discloses only R<sup>1</sup> and H, lower alkyl, or a cation, not the newly claimed groups." (It is noted that claims 27 and 35, wherein R<sup>1</sup> is H, CH<sub>3</sub>, CH(CH<sub>3</sub>)<sub>2</sub> or C(CH<sub>3</sub>)<sub>3</sub> are not rejected under 35 USC § 112.)

The applicants disagree with this rejection for the following reasons. The claims, as filed, are part of the specification. Therefore the claims themselves disclose the "newly added groups", i.e. the compounds wherein R<sup>1</sup> is other than "H, lower alkyl or a cation". Moreover, there is support for the claimed invention at least dating back to the filing of the parent of this patent application, i.e. U.S. Patent Application Serial No. 605,567 (the "Parent Application"), which parent application was filed on February 22, 1996, and has an ultimate effective filing date through its grand parent application i.e. U.S. Patent Application Serial No. 948,056 of September 21, 1992. (This point is discussed further, below.)

The Examiner has also rejected claims 26-45 under 35 USC § 102(e) as being anticipated by Bishop et al U.S. i.e. U.S. Patent 5,510,383. (The claims of the present application were copied from Bishop.) In fact, the Examiner has argued that "(c)laims 26-45 of this application has been copied by the applicant from U.S. Patent No. 5,510,383.

These claims are not patentable to the applicant because they are rejected under 35 USC § 112, first paragraph and under 35 102(e) above. An interference cannot be initiated since a prerequisite for interference under 37 CFR § 1.606 is that claims be patentable to the applicant subject to a judgement in the interference." (Note, the Examiner has not rejected claims 27 and 35 under 35 USC § 112, first paragraph, therefore as to these claims, at least, the 35 USC § 102(e) rejection is incorrect.) However, as stated above, the claims are fully supported, in accordance with 35 USC § 112, by at least the Parent Application which has a filing date of February 22, 1996. This filing date is prior to the April 23, 1996, date of issue of Bishop. Therefore Bishop cannot be used as a reference against the present claims under 35 USC § 102(e).

This support in the '567 Application for element R<sup>1</sup>\* of the present claims may be taken from original claim 1 of the '567 Application as follows:

Present Application

R<sup>1</sup> is hydrogen

R<sup>1</sup> is C<sub>1</sub>-C<sub>12</sub> alkyl,  
cycloalkyl aryl

R<sup>1</sup> is a  
pharmaceutically  
acceptable amine

'567 Application

Claim 1, X is OR<sup>4</sup> and R<sup>4</sup> may be  
hydrogen

Claim 1, R<sup>4</sup> may be lower alkyl  
(For the purpose of the present  
invention a alkylester is  
considered by the applicants as  
equivalent to the cycloalkyl or  
aryl ester of Bishop.)

Claim 1, compound of formula I  
includes pharmaceutically-  
acceptable salts (An amine is a  
pharmaceutically acceptable salt.)

\*The basis for rejecting the present claims under 35 USC § 112, first paragraph, is limited to lack of support for the "newly added groups" comprising R<sup>1</sup>. Applicants below reiterate the support found in the '567 Application for all of the elements of the present claims.

Present Application

R<sup>1</sup> is a cationic salt

Claim 26

R<sup>2</sup> is Cl or CF<sub>3</sub>

Claim 27

R<sup>1</sup> is H, CH<sub>3</sub>,  
CH(CH<sub>3</sub>)<sub>2</sub> and C(CH<sub>3</sub>)<sub>3</sub>

Claim 28

R<sup>1</sup> is Na<sup>+</sup> or CH<sub>3</sub>N<sup>+</sup>  
(CH<sub>2</sub>OH)<sub>3</sub>

Claim 29

R<sup>2</sup> is Cl

Claim 30

R<sup>2</sup> is CF<sub>3</sub>

Claims 31-33

Between about 0.001  
and about 1000  
μg/eye of compound  
is administered

Claims 34-41

Cover ophthalmic  
Compositions useful  
in the method of claims  
26-33, respectively.  
The limitations of these  
claims mirror the  
limitations of the  
previously discussed  
method claims

'567 Application

Claim 1, compound of formula I,  
includes pharmaceutically-  
acceptable salts (See also page  
13, line 5, wherein the salt  
may be an alkali metal salt,  
i.e. a cationic salt.)

Claim 4, Y<sup>1</sup> is Cl or  
trifluoromethyl

Claim 1 R<sup>4</sup> may be hydrogen  
or lower alkyl. See also,  
page 10, lines 25 and 26  
wherein lower alkyl includes  
methyl, propyl and butyl

Claim 1 includes pharmaceutically-  
acceptable salts. See also, page  
13, line 5 wherein salt includes  
alkali metal salts

See claim 4 wherein Y<sup>1</sup> is Cl

See claim 4 wherein Y<sup>1</sup> is  
trifluoromethyl

See page 13, lines 12-14  
"therapeutically efficient amount  
is between about 0.0001 and 5%  
(w/v), preferably about 0.001  
to about 1.0% w/v"

Claim 42\*  
R<sup>1</sup> is a X is -OR<sup>4</sup>,  
pharmaceutically  
acceptable ester  
moiety

See Claim 1; wherein Z is =0 and  
wherein R<sup>4</sup> is a  
lower alkyl

R<sup>2</sup> is Cl or CF<sub>3</sub>

See claim 4 wherein Y<sub>1</sub> is Cl or Trifluoromethyl

Claims 43-45

(See discussion above.)

The Examiner may wish to consider that the present claims were first presented in the '567 Application and were rejected under 35 USC § 102 over Bishop. In response the applicants' argued that they disagreed with "the Examiner's rejection of original claims 1-4, 8, 10, 12, 13, 14, 18 and 20-25 under 35 USC § 102 as being anticipated by Bishop, .... First, it is clear that the applicants have disclosed that the alkenylene linking the omega chain to the cyclopentane ring may be substituted with the oxo group. This would include an oxo group at the terminal portion of the alkenyl radical wherein said radical links to B. This provides support for an O-alkenylene linking moiety as found in fluprostenol and cloprostenol. It is further clear that the applicants disclose in Example I, the compound 16-m-chlorophenoxy PGF<sub>2α</sub> which is a specific example of a compound wherein the omega chain comprises oxygen-alkenylene linking group. This compound is also shown at Table V to be an effective IOP lowering agent both as an acid and as the 1-hydroxyl and 1-amido derivatives thereof. Note the methyl ester and the amido derivatives of 16-m-chloro phenoxy PGF<sub>2α</sub> are prepared in Examples 8 and 9 of the present specification while the 1-hydroxy derivative is prepared in Example 15 of such specification. In addition to the above,

\*It is not understood why the Examiner has rejected claims 42 through 45 under 35 USC § 112, first paragraph, since when R1, of the present claims is lower alkyl, (which the Examiner has accepted) the 1-position of the compound comprises an ester.

the Bishop reference is not a statutory bar. That is, the publication date of Bishop is less than a year from the filing date of the present application. Thus applicant concurrently herewith submits a Declaration Under Rule 1.131 which demonstrates that prior to the filing date of Bishop, the applications had reduced to practice the present invention as related to fluprostenol in the United States." (A copy of the Declaration under 37 CFR § 1.131 is attached to this reply for the Examiner's reference.)

The Examiner has rejected claims under 35 USC 135(b) as not being made prior to one year from the date on which U.S. Patent No. 5,510,383 was granted.

The applicants disagree with this rejection. In particular, the claims of the present invention were first presented in an amendment to the '567 Application, which amendment was filed on April 23, 1997. The issue date of Bishop is April 23, 1996, therefore the present claims were timely filed in accordance with 35 USC § 135(b). (See Switzer v. Sockman 380 U.S. 906, 1964.)

In view of the above, the Examiner is requested to reconsider and withdraw his rejection.

Respectfully submitted,



Robert J. Baran  
Registration No. 25,806  
Telephone: 714/246-4669  
Facsimile: 714/246-4249

ROBERT J. BARAN  
Legal Department (T2-2E)  
Allergan, Inc.  
2525 Dupont Drive  
Irvine, CA 92612

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